DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 25 2000

NDAs 18-687/S-021
18-686/S-026

Schering Corporation
Attention: Joseph F. Lamendola, Ph.D.
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Lamendola:

Please refer to your supplemental new drug applications dated December 6, 1999 (NDA 18-687) and March 13, 2000 (NDA 18-686), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Normodyne (labetalol hydrochloride) 100, 200 and 300 mg Tablets (NDA 18-687) and Normodyne (labetalol HCl) 5 mg/ml Injection.

These supplemental new drug applications provide for final printed labeling revised to add the following statement to the end of the CONTRAINDICATIONS section:

> Betablockers, even those with apparent cardioselectivity, should not be used in patients with a history of obstructive airway disease, including asthma.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package inserts included with your December 6, 1999 and March 13, 2000 submissions). Accordingly, the supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research